JUN 1 6 2009

Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device
510(k) Summary

K090721 p. 1/3

I. Applicant Information

Date Prepared	March 17, 2009
Submitter	Medtronic, Inc.
Address	710 Medtronic Parkway, NE Minneapolis, MN 55432
Establishment Registration Number	2135394
Contact Person	Peter Liu Sr. Regulatory Affairs Specialist

II. Device Information

Trade Name	Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device (Model 49205)
Classification Name	Electrosurgical cutting and coagulation device and accessories.
Classification	Class 2, 21 CFR 878.4400 Class 2, 21 CFR 870.3680
Product Code	OCL LDF
Device Description	The Medtronic Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device is a hand held, monopolar, radiofrequency ablation device powered by the Cardioblate® 68000 Generator (cleared via K060400, K080509). It has a saline irrigation system that delivers fluid at the contact point between tissue and electrode tip to cool tissue during radiofrequency energy delivery. The device can also be used with the Medtronic Model 2090/2290 Programmer/Analyzer and the Medtronic Model 5388/5348 External Temporary Pacemaker for two pole sensing of the ventricle or the atrium and two pole stimulation (pacing) of the atrium. The device is intended for intermittent operation. The device is provided sterile (via ethylene oxide sterilization), nonpyrogenic, disposable and for single use only.

Intended Use	The Medtronic Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device is a sterile, single use electrosurgery device intended to ablate cardiac tissue using radiofrequency energy when connected to the Cardioblate® 68000 Generator or for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to an external temporary cardiac pacemaker.
Contraindications	The Medtronic Cardioblate® System is contraindicated for patients that have active endocarditis at the time of surgery. The Medtronic Cardioblate® System is contraindicated for ablation in a pool of blood (e.g., through a purse string suture on a beating heart). Effects of this type of ablation have not been studied.
Predicate Device 1	Medtronic Cardioblate® Monopolar Pen K070288 (cleared June 18, 2007), K080509 (cleared May 5, 2008); Reg 878.4400, Product Code: OCL Predicate Indications: The Cardioblate® Monopolar Pen is a sterile, single use electrosurgery device intended to ablate cardiac tissue using radiofrequency energy when connected to the Cardioblate® generator or for temporary cardiac pacing, sensing, recording and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker.
Predicate Device 2	Medtronic Detect Surgical Pacing and Mapping Tool K040812, cleared September 2, 2004, Reg 870.3680, Product Code: LDF Predicate Indications: The Detect™ Surgical Pacing and Mapping tool is a hand held, single use device designed to provide temporary cardiac pacing or monitoring

III. Summary of Technological Characteristics Compared to Predicate Devices

The MAPS device has the same indications for use as the Monopolar Pens. The MAPS device is also capable of producing irrigated, monopolar radiofrequency ablations on cardiac tissue in a manner functionally equivalent to the existing Cardioblate Monopolar Pens and bipolar sensing, pacing, and mapping in a manner functionally equivalent to the existing Detect device. The change to bipolar mapping, pacing, and sensing results in greater clarity and reduced noise, and does not raise new types of safety and effectiveness questions.

IV. Brief Discussion of Non-Clinical Performance Data

Verification and validation testing, including bench testing and animal studies, were performed on the MAPS device, demonstrating equivalence to predicate devices.

V. Conclusions from Non-Clinical Data

Based upon the technical information, intended use, *in vitro*, *in vivo*, and clinical performance information provided in previous pre-market notifications, the Medtronic Cardioblate MAPS device described in this submission has been shown to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2009

Medtronic, Inc.
c/o Mr. Peter Liu
Sr. Regulatory Affairs Specialist
710 Medtronic Parkway
Minneapolis, MN 55432-5604

Re: K090721
Trade/Device Name: Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device (Model 49205)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OCL, LDF
Dated: March 17, 2009
Received: March 18, 2009

Dear Mr. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090721

Device Name: Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device (Model 49205)

Indications for Use:

The Medtronic Cardioblate® MAPS Surgical Mapping, Ablation, Pacing, and Sensing Device is a sterile, single use electrosurgery device intended to ablate cardiac tissue using radiofrequency energy when connected to the Cardioblate® 68000 Generator or for temporary cardiac pacing, sensing, recording, and stimulation during the evaluation of cardiac arrhythmias during surgery when connected to an external temporary cardiac pacemaker.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BZuckerman

(Division Sign-Off) 4/6/09
Division of Cardiovascular Devices

510(k) Number K090721